SECTION 7 **510(K) SUMMARY OF SAFETY AND EFFECTIVENESS**

K011202

7.1
Statement: DEC 31 2001

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.92

7.2
Submitter:

Medical Scientific, Inc.
125 John Hancock Rd.
Taunton, MA. 02779

7.3
Company Contact:

Paul Nardella
President
508-880-7313

7.4
Device Name

Proprietary Name: MSI Bipolar Sheath
Common Name: Bipolar Coagulation Device
Classification Name: Electrosurgical cutting and coagulation device and accessories

7.5
Predicate Legally Marketed Devices:

The Bipolar Sheath is substantially equivalent to the Endius Bipolar Sheath manufactured by Endius, Inc. (Plainville, MA) and the SLT Bipolar Sheath manufactured by Surgical Laser Technologies (Montgomery, PA).

7.6
Device Description:

The MSI Bipolar Sheath is a stainless Steel tube covered with an insulation material that is intended to fit over an automated tissue removal blade. The device is intended to be connected to electrosurgical generators with bipolar output with capability of delivering 70 Watts into a 40 ohm load. The maximum output voltage can not be greater than 800 volts peak to peak. The device can be connected to the Valley Lab's Force 2 generator by using the Bipolar Sheath Adapter which is intended to decrease the maximum voltage of the Valley Lab's Generator. This will ensure that the appropriate level of energy is transmitted to the Bipolar Sheath for the maximum performance.

7.7
Device Indications and Intended use:

The MSI Bipolar Sheath is intended to be used in conjunction with the powered debrider cutter systems to cut and coagulate soft tissue during various arthroscopic surgical procedures.

7.8
Substantial Equivalence:

The MSI Bipolar Sheath is substantially equivalent to both the Endius Bipolar Sheath manufactured by Endius, Inc.(Plainville, MA) and the SLT Bipolar Sheath manufactured by Surgical Laser Technologies (Montgomery, PA).

Table of Substantial Equivalence			
Device Name	Endius Bipolar Sheath	SLT Bipolar Sheath	MSI Bipolar Sheath
Intended Use	**K003897:** The Endius Bipolar Sheath is intended to be used to coagulate soft tissue during various spinal surgical procedures.	**K981041:** The SLT Bipolar Sheath is intended to be used to coagulate soft tissue during ENT procedures. **K984018:** The SLT Bipolar Sheath is intended to be used to coagulate soft tissue during orthopedic procedures.	The MSI Bipolar Sheath is intended to be used to coagulate soft tissue during arthroscopic procedures.
Material	Stainless Steel, parylene coating, Plastics and adhesives	Stainless Steel, polyethylene	Stainless Steel, parylene coating, Plastics and adhesives
Sterilization/ Labeling	Single Use, Sterilized by gamma irradiation	Single Use, Sterilized by 100% Ethylene Oxide	Single Use, Sterilized by 100% Ethylene Oxide
Size	3.5mm - 4.5mm	3mm - 5mm	3mm - 5.5mm
Exposed Tip Size	20mm area maximum	4.5mm area	20mm area maximum
Length	12cm - 23cm	8.3cm (varies depending on length of blade)	12cm - 23cm
Operating Mode	To be used with ESU generators in Bipolar Mode	To be used with ESU generators in Bipolar Mode	To be used with ESU generators in Bipolar Mode

Applicant Paul Nardella Date 4-11-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 31 2001

Mr. Paul Nardela
President
Medical Scientific, Inc.
125 John Hancock Road
Taunton, Massachusetts 02780

Re: K011202
Trade Name: MSI Bipolar Sheath
Regulation Number: 878.4400
Regulation Name: Arthroscope and accessories; Electrosurgical cutting and coagulation device and accessories;
Regulatory Class: II
Product Code: HRX; GEI
Dated: October 1, 2001
Received: October 9, 2001

Dear Mr. Nardela:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011202

Device Name: MSI Bipolar Sheath

Indications For Use:

The MSI Bipolar Sheath is intended to be used in conjunction with the powered debrider cutter systems to cut and coagulate soft tissue during various arthroscopic surgical procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE. CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011202